

REMARKS

Claims 13-20 were pending in the present application. Claims 13 and 17 have been amended herein, support for which can be found at, for example, page 8, lines 14-22 of the specification. New claims 21-24 have been added herein, support for which can be found at, for example, page 8, lines 14-22 of the specification. No new matter has been added. Upon entry of the present amendment, claims 13-24 will be pending.

I. Objections

The Action objects to the drawings, alleging that they fail to comply with 37 C.F.R. §1.84(p)(5) because they do not include reference signs “1” and “2” mentioned in the description, and because they include reference character “3” which is not mentioned in the description. *See* Action at page 2. Applicant has submitted a Replacement Sheet herewith which identifies reference signs “1” and “2” and which does not include reference character “3.” Support for the Replacement Sheet can be found at page 17, lines 10-15 of the specification. Accordingly, Applicant respectfully requests that the drawing objections be withdrawn.

II. The Claimed Invention is Novel

Claims 13, 15-17, 19, and 20 stand rejected under 35 U.S.C. §102(b) as being anticipated by Perlman et al., U.S. Patent No. 4,526,752 (hereinafter the “Perlman reference”). Applicant respectfully requests reconsideration because the Perlman reference does not teach every element of the claimed invention.

As can be seen from the application as filed, one element of the present invention is the period of latency after the packaging surrounding the device containing the marking is opened and exposed to ambient conditions. In other words, the marking is “latent” for the period of time after the package is opened until a predetermined time after which the marking becomes visible. *See* Specification at page 15, lines 3-7. The system described in the present application can be seen more in terms of being an alarm clock that goes off after a pre-set time. A message or symbol is displayed after a predetermined time lapse following exposure to ambient conditions. The aforementioned display does not happen gradually, nor does it happen immediately after

exposure to ambient conditions (or rupturing in error). The marking becomes visible only after the predetermined time has elapsed.

The three periods of time in regard to the claimed invention can be thought of as follows:

1. Inactive phase – prior to the opening of the packaging, in which the latent marking remains invisible and undeveloped;
2. Latent phase – a predetermined time period after opening of the packaging materials and exposure of the latent marking to ambient conditions, in which no marking is visible; and
3. Visible phase – commences only after the pre-determined time (or latent phase) has expired and the latent marking become visible.

To further advance prosecution of the present application, claims 13 and 17 have been amended to make this latent period even more clear. In particular, claims 13 and 17 have been amended to recite “wherein the latent marking does not become visible immediately following exposure of the medical device to air.” Support for this amendment can be found at, for example, page 8, lines 14-22 of the specification where Applicant distinguishes between immediate visibility of the latent marking after exposure versus visibility after a predetermine time. In addition, Applicant has added new claims 21-24, support which can also be found at, for example, page 8, lines 14-22 of the specification.

In stark contrast to the present invention, Applicant is unable to locate any portion of the Perlman reference that teaches a system containing a time release or delay element to permit visibility of the marking after a pre-determined time period. Indeed, the Perlman reference reports a dye that *immediately* transforms to the colored state when oxygen is admitted – as would take place with the opening of the package. *See* Perlman reference at col. 1, lines 59-64. Thus, the Perlman reference does not teach every element of the claimed invention.

Accordingly, Applicant respectfully asserts that the claimed invention is novel and requests that the claim rejection be withdrawn.

III. The Claimed Invention is Not Obvious

Claims 14 and 18 stand rejected under 35 U.S.C. §103(a) as allegedly being unpatentable over the combination of the Perlman reference and U.S. Patent No. 4,987,849 (hereinafter, the "Sherman reference). Applicant respectfully requests reconsideration because the combination of the cited references does not result in the claimed invention.

As stated above, the Perlman reference does not teach or suggest a medical device in which a latent marking becomes visible after a predetermined time (in contrast to immediate visibility of the latent marking). The Sherman reference is not identified by the Examiner as being able to cure this deficiency. Thus, the combination of the Perlman and Sherman references does not result in Applicant's claimed invention.

Accordingly, Applicant respectfully asserts that the claimed invention is not obvious, and requests that the claim rejection be withdrawn.

III. Conclusion

Applicant respectfully submits that the claims are in condition for allowance. An early notice of the same is earnestly solicited. The Examiner is invited to contact Applicant's undersigned representative at (610) 640-7859 to resolve any remaining issues.

The Commissioner is hereby authorized to debit any underpayment of fee due or credit any overpayment to Deposit Account No. 50-0436.

Respectfully submitted,

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Date: **December 31, 2007**

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